b) [hot filtering] treating the first liquid with a hot filtering process selected from the group consisting of liquid:liquid centrifugation, submicro/microfiltration, liquid:liquid coalescers and absorbents and combinations thereof to form a second liquid containing gelatin having a higher purity than the first liquid.

REMARKS

The foregoing amendment is submitted to more clearly set forth the claimed invention and to address the technical objections to the claims as set forth on page 2 of the Office Action. In particular, claim 1 has been amended to insert the word "first" to define the initial liquid which is produced in accordance with the claimed process. Proper antecedent basis is now found for the expression "first liquid" as it appears in the last line of claim 1.

Claims 11, 13, 14, 18, 19, 49-52, 56 and 57 have been amended to conform the subject matter of these claims to the specific language of claim 1. In particular, proper antecedent basis has been provided for the terms "residual oils" and "particulates". Claims 23 and 64 have been amended to meet the objection set forth at the bottom on page 2 of the Office Action regarding use of the term "polyol". Claim 44 has been amended to depend from claim 1 wherein claim 44 adds the further step of treating the non-solvent based layer by distillation or reverse osmosis to remove oily components therefrom. Claim 45 has been canceled because the subject matter thereof is included

in claim 1. Finally, claim 70 has been amended to provide the specific hot filtering processes referred to in claim 1. This amendment is deemed to obviate the rejection of claims 44-45 and 70 as anticipated by Schmidt et al., U.S. Patent No. 5,288,408.

No new matter has been added by the amendment to Applicant's claims and entry thereof is deemed proper and is respectfully requested.

As indicated on page 2 of the Office Action, claim 1 is objected to for use of the term "submicro/microfiltration". The Office Action questions the intent of this recitation. The rejection is hereby traversed and reconsideration is respectfully requested.

Page 15 of the specification provides a detailed description of the term "submicro/microfiltration" which refers to a method of removing small particles from a liquid. This filtration process can be achieved through the use of micron or submicron pore sized filters including, but not limited to cartridge-type filters and tangential flow-type filters with a preferred pore size typically in the range of from about 0.1 to 2.0 microns which is necessary to remove residual oils and particulates typically found in a waste material containing gelatin obtained from the manufacture of soft gel capsules. In the first two paragraphs on page 16 of the specification, temperature and dilution information is provided as well as a source of submicro and microfiltration equipment. It is therefore submitted that the specification provides sufficient details as to the type of equipment necessary to perform submicro and microfiltration, the process conditions which may be employed and where such equipment can be purchased. The

information provided in the specification is therefore deemed to be complete and fully satisfy the requirements of 35 U.S.C. Section 112.

Several of the claims have been objected to for use of the term "short path distillation". The rejection is hereby traversed and reconsideration is respectfully requested.

Beginning with the last full paragraph on page 18 of the specification, the term "short path distillation" is described in such clear and exact terms as to enable any one of ordinary skill in the art to make and use the same as it applies to the present invention. The purpose of short path distillation is to employ moderate temperatures and short contact times in a distillation procedure so as not to cause decomposition of the protein-based gelatin which affects its bloom strength. The temperature of the process, the process pressures and the dilution ratios are clearly provided in the specification on pages 18 and 19. It is therefore submitted that one of ordinary skill in the art would understand the meaning of "short path distillation" and would understand how to conduct such a process within the context of the present invention. It is therefore submitted that the term "short path distillation" is properly defined in the application as filed and is fully enabling within the requirements of 35 U.S.C. Section 112.

Claims 1-5, 7-8, 10-27 and 44-70 stand rejected as obvious over Schmidt et al. (U.S. Patent No. 5,288,408) in view of any of Fane et al. or Dutre et al. or Chakravorty

et al. The Office Action states that Schmidt et al. disclose a method of gelatin recovery in which a waste material is dissolved in a solvent in an agitated tank and separated into an aqueous phase stream and an organic phase stream. It is stated that the resultant aqueous phase stream is then subjected to heat and hot filtered. The Office Action acknowledges that claim 1 differs from Schmidt et al. by specifying a step of treating the solvent based layer with a specific selection of hot filtering processes which are not taught or suggested by Schmidt et al. The Office Action then refers to the secondary references as disclosing the use of "microporous filtration techniques" to purify gelatin solutions. The Office Action concludes that it would have been obvious to one of ordinary skill in the art to incorporate one of the secondary reference "microporous filtration techniques" into Schmidt et al. to arrive at the claimed invention. The rejection is hereby traversed and reconsideration is respectfully requested.

Each of Fane et al., Dutre et al., Chakravorty et al. teach ultrafiltration as a technique for de-watering gelatin process liquors. On page 203 of Fane et al., ultrafiltration is described as a pressure-driven separation technique based on a semi-permeable membrane which allows the passage of water and ionic species but which restricts the passage of macromolecules and suspended solids. Chakrovorty et al. describes on page 280 the employment of ultrafiltration as a process which offers potential in de-watering gelatin liquor as macromolecules are rejected by membranes while water along with inorganic molecules (e.g. salts) are permitted to migrate across the membranes. Dutre et al. describes the ultrafiltration of a gelatin liquor containing sodium chloride. In particular, the references concerns diafiltration (i.e. ultrafiltration in

a dilution mode) as applied to a gelatin-sodium chloride containing solution. When diafiltration with a permeate-forced solvent stream is used instead of classical diafiltration, the efficiency of the process is improved.

Accordingly, each of the secondary references teaches ultrafiltration for the treatment of a gelatin raw material for dewatering. As will be apparent from the discussion below, the employment of such ultrafiltration techniques in the Schmidt et al. process would not lead one of ordinary skill in the art to the claimed invention nor would it provide an effective method of treating waste gelatin as claimed herein.

As explained in more detail below, the hot filtering processes specifically covered by the present claims including submicro/microfiltration are very different than the ultrafiltration techniques covered by the secondary references. Ultrafiltration is a distinct filtration technique from submicro/microfiltration in the manner in which separation is achieved and in its application to the specific process claimed in the present application. In Munir Cheryan, Ultrafiltration Handbook, a copy of which is enclosed (this reference was previously referred to in an Information Disclosure Statement), there are five major membrane filtration processes which include reverse osmosis, microfiltration, ultrafiltration, dialysis and electrodialysis which cover a wide range of particle sizes. Depending on the membrane construction, ultrafiltration can also be referred to as "microporous ultrafiltration".

Page 2 of Cheryan states that microfiltration processes are designed to retain particles in the "micron" range, that is, suspended particles in the range of 0.10 um to about 10 um. Page 4 states that microfiltration is also a method for essentially separating suspended particles from dissolved substances in a feed stream, provided the particles meet the requirements for microfiltration membranes. Microfiltration as applied in the present application is employed to remove particles from the dissolved gelatin, specifically emulsified oil and residual oil droplets in the "micron" range as described above. Microfiltration is a physical separation of dissolved and undissolved components of a process stream based on particle size. As will become apparent below, ultrafiltration techniques cannot remove oil droplets or emulsified oil from dissolved gelatin.

Ultrafiltration (or microporous ultrafiltration) as described in the secondary references is a filtration technique designed to preferentially separate different kinds of fluids or ions. Ultrafiltration is most commonly used to separate a solution having dissolved components to remove undesirable dissolved components. Microporous ultrafiltration is not capable of removing residual oil droplets or emulsified oils. In brief, ultrafiltration is concerned with solutions and removing different components within a solution while microfiltration separates suspended particles, including suspended oil particles, from a solution. Thus, microfiltration as that term is used as one of the hot filtering processes of the present claims is materially different than the ultrafiltration techniques disclosed by the secondary references.

The substitution of an ultrafiltration technique of the secondary references in the waste gelatin recovery process of Schmidt et al. can not and will not result in a method of treating a waste gelatin material that is capable of removing residual oils and/or particulates from the gelatin solution. If residual oils and particulates can not be removed from the waste gelatin steam, the process has no practical value. Ultrafiltration can not remove these materials because it is a technique solely directed to removing dissolved components from a solution. To the contrary, the stream which is treated in accordance with the present invention typically contains residual oils and particulates and their removal is essential for the production of a usual recyclable gelatin stream which may be forwarded to a capsule forming operation.

Thus, not only are the techniques of microfiltration and ultrafiltration materially different, their application as a substitute in the Schmidt et al. process provides materially different results. In particular, the employment of ultrafiltration does not remove residual oils or particulates from the waste gelatin material.

To the contrary, the employment of microfiltration as one of the hot filtering process techniques specifically covered in claim 1 removes residual oils and particulates from the waste gelatin stream and provides a usable product for recycling. This can not be achieved by substituting microporous ultrafiltration into the Schmidt patent as the purification step.

Subsequently, an ultrafiltration technique can be used to de-water the usable waste gelatin product to raise the concentration of gelatin in the waste stream but at this step of the process residual oils and particulates must have previously been removed.

It is therefore submitted that the claims of the application define a process which is neither taught nor suggested by the references of record. The combination of Schmidt et al. and the secondary references does not provide a teaching of a process of treating a waste material containing gelatin with a hot filtering technique which is sufficient to remove residual oils and particulates from the waste gelatin stream. The prior art does not teach or suggest a process for achieving this result and the disclosure of ultrafiltration as a means of treating a raw gelatin solution does not suggest the present process because the prior art process does not and can not remove residual oils or particulates. Instead, the prior art process set forth in the secondary references is concerned with treating a raw gelatin solution that contains ionic species (salts) for which ultrafiltration is an acceptable technique. This technique, is not suggestive of a technique for removing particulates, such as residual oil droplets, from a solution as Applicant has done to treat a waste gelatin solution resulting from the byproduct of soft gel capsule manufacturing processes.

In view of the foregoing, Applicant submits that the present application is in condition for allowance and early passage to issue is therefore deemed proper and is respectfully requested.

ARK:jsg110100/671002CIP-3.AMD2

It is believed that no fee is due, however, if any fee is due it should be charged to Deposit Account No. 23-0510.

Respectfully submitted,

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